DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 28, 2015

Tyber Medical LLC
Mr. Jeff Tyber
CEO and President
89 Headquarters Plaza North, #1464
Morristown, New Jersey 07960

Re: K150394
Trade/Device Name: Tyber Medical Wedge System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: PLF, HRS, HWC
Dated: June 19, 2015
Received: June 22, 2015

Dear Mr. Tyber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150394

Device Name
Tyber Medical Wedge System

Indications for Use *(Describe)*
PEEK System Indications

The Tyber Medical PEEK Wedge System is intended to be used for internal bone fixation for bone fractures or osteotomies in the ankle and foot such as:

- Cotton and Evans Wedges
  - o Opening wedge osteotomies of the bones of the foot including osteotomies for Hallux Valgus
  - o Opening wedge of Medial Cuneiform of Cotton osteotomies
  - o Lateral Column Lengthening (Evans Lengthening Osteotomy or Calcaneal Z Osteotomy)
- Midfoot Wedges
  - o Opening wedge osteotomies of the bones of the foot including osteotomies for Hallux Valgus
  - o Nonunion of arthrodesis of the Midfoot including Metatarsal/Cuneiform arthrodesis (TMT or Lapidus)

The device is intended for use with ancillary fixation
The Tyber Medical Wedge System is not intended for use in the spine

TyPEEK System Indications

The Tyber Medical TyPEEK Wedge System is intended to be used for internal bone fixation for bone fractures, fusions, or osteotomies in the ankle and foot such as:

- Cotton and Evans Wedges
  - o Opening wedge osteotomies of the bones of the foot including osteotomies for Hallux Valgus
  - o Opening wedge of Medial Cuneiform of Cotton osteotomies
  - o Lateral Column Lengthening (Evans Lengthening Osteotomy or Calcaneal Z Osteotomy)
- Midfoot Wedges
  - o Opening wedge osteotomies of the bones of the foot including osteotomies for Hallux Valgus
  - o Nonunion of arthrodesis of the Midfoot including Metatarsal/Cuneiform arthrodesis (TMT or Lapidus)

The device is intended for use with ancillary fixation
The Tyber Medical Wedge System is not intended for use in the spine

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary of Safety and Effectiveness:

TYBER MEDICAL Wedge System

Submitter by:
Tyber Medical LLC
89 Headquarters Plaza North, #1464
Morristown, New Jersey 07960

Contact Person
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Director of Quality and Regulatory
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Date Prepared
July 17, 2015

Common Names
Bone Wedge
Osteotomy Bone Wedge

Trade Name
Tyber Medical Wedge System

Classification Name and Number
Single/multiple component metallic bone fixation appliances and accessories (21 CFR 888.3030)
Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040)

Product Code
PLF, HRS and HWC

Primary Predicates Devices
1. WRIGHT MEDICAL; Biofoam – K140531

Reference Devices
1. IBALANCE MEDICAL; AKR FX Medical Opening Wedge Tibial System – K092381
2. TYBER MEDICAL; Tyber Medical Interbody System – K130573
3. LIFE SPINE; Pro-Link Wedge System – K141905

Device Description
The Tyber Medical Wedge System, manufactured from PEEK-Optima®, consist of implants available in various foot prints, heights and indication configurations with an open architecture to accept packing of bone graft materials. The exterior of the device has "teeth" or other generally sharp engagement members on the superior and inferior surfaces. The device comes in a PEEK or PEEK with a plasma-sprayed commercially pure titanium coating on the superior and inferior surfaces.

Intended Use/ Indications for use

PEEK System Indications
The Tyber Medical Wedge System is intended to be used for internal bone fixation for bone fractures or osteotomies in the ankle and foot such as:
- Cotton and Evans Wedges

- Opening wedge osteotomies of the bones of the foot including osteotomies for Hallux Valgus
- Opening wedge of Medial Cuneiform of Cotton osteotomies
- Lateral Column Lengthening (Evans Lengthening Osteotomy or Calcaneal Z Osteotomy)

- Midfoot Wedges
  - Opening wedge osteotomies of the bones of the foot including osteotomies for Hallux Valgus
  - Nonunion of arthrodesis of the Midfoot including Metatarsal/Cuneiform arthrodesis (TMT or Lapidus)

The device is intended for use with ancillary fixation
The Tyber Medical Wedge System is not intended for use in the spine

TyPEEK System Indications

The Tyber Medical Wedge System is intended to be used for internal bone fixation for bone fractures, fusions, or osteotomies in the ankle and foot such as:

- Cotton and Evans Wedges
  - Opening wedge osteotomies of the bones of the foot including osteotomies for Hallux Valgus
  - Opening wedge of Medial Cuneiform of Cotton osteotomies
  - Lateral Column Lengthening (Evans Lengthening Osteotomy or Calcaneal Z Osteotomy)
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Performance Data (Non-Clinical)

Non-clinical mechanical testing was performed consisting of Static Compression, Dynamic Compression, Static Compression-Shear, Static Torsion, Dynamic Torsion per ASTM F2077. Additionally, Expulsion testing was performed. The coating characterization tests include Static Shear per ASTM F 1044, Static Tension per ASTM F 1147, and Abrasion per ASTM F 1978. All data indicates the device is substantial equivalence to the predicate systems

Performance Data (Clinical)

Clinical data and conclusions were not needed for this device.

Statement of Technological Comparison

The Tyber Medical Wedge System and its predicate devices have the same indications for use; same design; are made of similar materials, same application, and have the same anatomic mechanical properties.

Conclusion

The Tyber Medical Wedge System is substantially equivalent to its predicate devices. This conclusion is based upon indications for use, materials, design, test data and principles of operation.